

## **Devyser receives MDSAP certification for Brazil**

**Devyser Diagnostics AB announces today that it has received Medical Device Single Audit Program (MDSAP) certification for its quality management system (QMS) for both Devyser assays and software in Brazil.**

The MDSAP certification for Brazil complements the company's existing certificates in the United States and Canada, reinforcing Devyser's commitment to meeting the highest standards of quality, safety, and regulatory compliance across multiple jurisdictions. With MDSAP certification for Brazil, the company is well-positioned to expand its reach and impact in the Latin American region.

MDSAP certification can potentially expedite the timeline for the commercialization of regulatory-approved products.

“Achieving another MDSAP certification confirms our ongoing commitment to maintaining the highest quality assurance standards for our products and accompanying software. This certification not only demonstrates our commitment to regulatory compliance, but also strengthens our position in the global marketplace, enabling us to better serve the needs of our customers,” said Fredrik Alpsten, CEO of Devyser.

Devyser is partnered with several distributors in Brazil including Thermo Fisher Scientific and Biometrix.

MDSAP is a regulatory initiative designed to streamline and harmonize the audit process for medical device manufacturers, enabling a single audit to satisfy the QMS requirements of participating regulatory authorities, such as FDA, ANVISA, Health Canada, among others.

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### **About Devyser**

Devyser develops, manufactures and sells diagnostic solutions and analysis services to clinical laboratories in more than 65 countries. Our products are used for advanced genetic testing in the hereditary disease, oncology and transplant fields, to enable targeted cancer treatment, the diagnosis of a large number of genetic diseases, and transplant patient follow-up. Devyser's products, and unique, patented solution requiring only one test tube, simplify genetic testing processes, improve sample throughput, minimize hands-on time and deliver rapid results. Our goal is for every patient to receive a correct diagnosis in the shortest possible time. Sustainability is a central part of our business and an important prerequisite for long term value creation.

Devyser was founded in 2004 and is based in Stockholm, Sweden with eight in-house sales offices in Europe and the US. The company also runs Devyser Genomic Laboratories, a CLIA certified laboratory in Atlanta, US. In 2022, Devyser's quality management system was certified according to the IVDR and a number of the company's products have since been certified according to the IVDR.

Devyser's shares are listed on the Nasdaq First North Premier Growth Market Stockholm (ticker: DVYSR). The company's Certified Adviser is Redeye AB.

For more information, visit [www.devyser.com](http://www.devyser.com).